

Amendment

U.S.S.N. 09/966,202

Attorney Docket R008613-DIV

*APPENDIX A**Clean Copy of Amended Claims*

1. A method of treating emphysema in a mammal comprising administering to a mammal in need of such treatment a therapeutically effective amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof.
2. (cancelled)
3. (canceled)
4. (cancelled)
5. (canceled)
6. The method of Claim 1, wherein the therapeutically effective amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, repairs alveoli in the mammal.
7. The method of Claim 1, wherein the mammal is human.
8. The method of Claim 7, wherein the human was or is a cigarette smoker.
9. The method of Claim 1, wherein the emphysema is panlobar emphysema, centrilobular emphysema or distal lobular emphysema.
10. The method of Claim 1, wherein the therapeutically effective amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof is administered with an electrohydrodynamic aerosol device.
11. (amended) A pharmaceutical composition suitable for treating a mammal suffering from emphysema comprising an amount of 13-*cis*-retinoic acid or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof and a pharmaceutically acceptable carrier, said amount being sufficient to alleviate at least one symptom of emphysema.
12. (amended) The pharmaceutical composition of Claim 36, wherein the pharmaceutically acceptable carrier is suitable for electrohydrodynamic aerosol device, a aerosol device or a nebulizer device.

Amendment  
USSN 09/966,202

Attorney Docket R0086B-DIV

13. (amended) The pharmaceutical composition of Claim 36, wherein the amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, is between about 0.1  $\mu$ g and about 10.0 mg.
14. The pharmaceutical composition of Claim 13, wherein the amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, is between about 1.0  $\mu$ g and about 1.0 mg.
15. The pharmaceutical composition of Claim 14 wherein the amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof is between about 100.0  $\mu$ g and about 300.0  $\mu$ g.
16. The pharmaceutical composition of Claim 12, wherein the pharmaceutically acceptable carrier is a liquid.
17. The pharmaceutical composition of Claim 16, wherein the pharmaceutically acceptable carrier is chosen from the group consisting of water, alcohol and perfluorocarbon.
18. The pharmaceutical composition of Claim 16, wherein the amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof is between about 1.0  $\mu$ g and about 100.0  $\mu$ g.
19. The pharmaceutical composition of Claim 18, wherein the amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof is between about 3.0  $\mu$ g and about 30.0  $\mu$ g.
20. The pharmaceutical composition of Claim 19, wherein the amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof is between about 5.0  $\mu$ g and about 15.0  $\mu$ g.
21. The method of Claim 9, wherein the mammal is human.
22. The method of Claim 21, wherein the human was or is a cigarette smoker.

Amendment  
USSN 09/966,202

Attorney Docket R0086B-DIV

23. (amended) The method of Claim 11, wherein the emphysema is panlobar emphysema, centrilobular emphysema or distal lobular emphysema.
24. A method for treating emphysema and related disorders comprising delivering a formulation of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, into the lungs of a mammal.
25. The method of Claim 24, wherein the emphysema is panlobar emphysema, centrilobular emphysema or distal lobular emphysema.
26. The method of Claim 25, wherein the mammal is human.
27. The method of Claim 26, wherein the human was or is a cigarette smoker.
28. The method of Claim 24, wherein the formulation is delivered into the lungs of the mammal with a nebulizer device.
29. (amended) The method of Claim 24, wherein the formulation is delivered into the lungs of the mammal with an aerosol device.
30. (amended) The method of Claim 24, wherein the formulation is delivered into the lungs of the mammal with an electrohydrodynamic aerosol device.
31. A method for treating emphysema comprising combining the use of 13-*cis*-retinoic acid with one or more additional therapies.
32. The method of Claim 31, wherein the additional therapies are chosen from the group consisting of smoking cessation, bronchodilators, antibiotics and oxygen therapy.
33. A method for preventing emphysema in a human at risk of emphysema comprising administering to the human a amount of 13-*cis*-retinoic acid, or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, said amount being sufficient to prevent emphysema.

Amendment  
USPN 09/966,202

Attorney Docket R0086B-DIV

34. The method of Claim 33, wherein the human was or is a cigarette smoker.
35. A pharmaceutical composition suitable for preventing emphysema in a human at risk of emphysema comprising an amount of 13-*cis*-retinoic acid or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof and a pharmaceutically acceptable carrier, said amount being sufficient to prevent emphysema.
36. (new) A pharmaceutical composition according to claim 11 wherein the pharmaceutical composition is suitable for administration to the lungs by inhalation.
37. (new) A pharmaceutical composition according to claim 35 wherein the pharmaceutical composition is suitable for administration to the lungs by inhalation.
38. (new) A pharmaceutical composition for treating a mammal suffering from chronic obstructive pulmonary disease comprising an amount of 13-*cis*-retinoic acid or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof, and a pharmaceutically acceptable carrier, said amount being sufficient to alleviate at least one symptom of chronic obstructive pulmonary disease.
39. (new) A pharmaceutical composition according to claim 38 wherein the pharmaceutical composition is suitable for administration to the lungs by inhalation.
40. (new) A pharmaceutical composition suitable for preventing chronic obstructive pulmonary in human comprising an amount of 13-*cis*-retinoic acid or a pharmaceutically acceptable salt, hydrate, solvate, or pro-drug thereof and a pharmaceutically acceptable carrier, said amount being sufficient to prevent chronic obstructive pulmonary disease, wherein said pharmaceutical composition is in a form suitable for administration to the lungs by inhalation.
41. (new) A pharmaceutical composition according to claim 40 wherein the pharmaceutical composition is suitable for administration to the lungs by inhalation.
42. (new) The pharmaceutical composition of Claim 36, wherein said form is suitable for administration through a metered dose inhaler.

Amendment  
USSN 09/966,202

Attorney Docket R0086B-DIV

43. (new) The pharmaceutical composition of Claim 36, wherein said form is suitable for administration through a dry powder inhaler.
44. (new) The pharmaceutical composition of Claim 36 wherein said form is suitable for administration through a liquid spray device.
45. (new) The pharmaceutical composition of Claims 44, wherein said liquid spray device is an aerosol device.
46. (new) The pharmaceutical composition of Claim 45, wherein said aerosol device is a nebulizer or electrohydrodynamic aerosol device.
47. (new) The pharmaceutical composition of Claim 41, wherein the chronic obstructive pulmonary disease is emphysema or chronic bronchitis.

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